

REQUEST FOR RECONSIDERATION

Applicants thank Examiner Patterson for the helpful and courteous discussions of February 19 and May 23, 2004. During the discussion, Applicants' U.S. representative presented arguments and information showing that those of ordinary skill in the art would readily recognize the *E. coli* JM109 bacterium and its plasmids pOM22 and pOM21.

In the Advisory Action of May 6, 2004, the Office refused entry of the Amendment filed on April 21, 2004 on the grounds that the sequence identification numbers appearing in the text incorporated by reference in the original specification and now incorporated explicitly by amendment are duplicative of at least sequence identification numbers 1-6 present in the original specification. The present Amendment and Request for Reconsideration renames the sequence identification numbers of the text which is included in the present specification by amendment to take into account the original six sequence identification numbers of the original specification. Therefore, sequence identification No. 1 of the text added to the specification in the present Amendment is now identified as sequence identification No. 7. Each of the other sequence identification numbers of the new text has been correspondingly changed.

In the Advisory Action it is noted that the proposed amendments were also not entered because they may raise new issues requiring further consideration or may raise the issue of new matter. Applicants submit that the amendment to the specification does not raise any new issues because the information added by the present amendment to the specification was incorporated by reference in the specification as originally filed. Therefore the text added by amendment also does not represent new matter.

The present Amendment is substantially the same as the Request for Reconsideration filed on April 21, 2004.

In the Office Action of February 23, 2004, the Office objected to the term JM109 (pOM22, pOM21) on the grounds that it is essential material incorporated by reference in the present application. Applicants submit that those of ordinary skill in the art readily recognize that JM109 may be a commercially available *Escherichia coli* bacterium.

The Office has objected to the specification on the grounds that the term *E. coli* JM109 (pOM22, pOM21) is essential matter that must be disclosed in the specification. The term JM109 (pOM22, pOM21) is identified in the application as originally filed on page 7, lines 13 -14 by reference to U.S. 60/157,427. Applicants submit that those of ordinary skill in the art would readily recognize that the details of JM109 (pOM22, pOM21) are those materials disclosed in U.S. 60/157,427. The details of the JM109 *E. coli* cells of 60/157,427 are also described in U.S. 6,524,837 which provides 60/157,427 as a related U.S. application.

The whole cell catalyst JM109 (pOM22, pOM21) which has a cloned gene coding for a hydantoin racemase, a hydantoinase and a L- or D-specific carbamoylase has now been explicitly included in the present specification by the above-mentioned amendment. The amendment does not represent new matter because both U.S. 60/157,427 and U.S. 09/407,062 are incorporated by reference in the specification as originally filed (page 5, line 12-13).

Applicants submit that the amendment to the specification to include at least a portion of the information incorporated by reference in the specification as originally filed obviates the Office's objection to the specification with regard to the term JM109 (pOM22, pOM21).

Applicants submit the amendment further overcomes the rejection in view of 35 U.S.C. § 112, first paragraph with regard to Applicants' possession of the claimed invention and the disclosure's sufficiency for allowing those of ordinary skill in the art to make or use the claimed invention. Applicants submit the amended specification sufficiently describes the process of Claims 1 and 19.

The Office objected to the present specification on the grounds that the language of the claims is not taught in the specification. Specifically the Office noted;

“the instant specification does not teach “contacting a hydantoin of...formula II...with a hydantoinase and a D- or L- specific carbamolayse in the presence of at least one hydantoin racemase under conditions suitable for the *in situ* racemisation of the hydantoin of an N-carbamoyl amino acid” as claimed in claim 1 or the embodiments of claim 19... Therefore it is continued to be maintained that the claimed invention was not described in the specification in such a way as to show the skilled artisan that they had possession of the claimed invention and/or in such a way as to enable this artisan to make and/or use the invention...”

The specification as amended above to clarify the term JM109, discloses that the hydantoinase is expressed in *E. coli* JM109 (see for example column 7, lines 13-27 of U.S. 6,524,837). Further, it is disclosed that whole cell catalysts may be prepared by co-expressing the evolved or wild-type hydantoinase with a hydantoin, a racemase and a L-carbamolyase in *E. coli* (column 9, lines 21-24). Thus the specification as originally filed discloses a process of preparing compounds of formula (I) through an enzymatic process performed on a hydantoin of formula (II) (page 1, lines 5-9).

On page 4, lines 18-26 of the specification as originally filed it is disclosed:

“Compounds of formula (II) are subjected to a reaction with at least one hydantoinase and at least one D- or L-specific carbamoylase, as well as to a spontaneous and/or enzyme-catalyzed *in situ* racemisation.”

Therefore, the specification as originally filed explicitly discloses that which the Office asserts is not taught (see also page 5, lines 30-35). The conditions under which the process is carried out are disclosed beginning at page 5, line 27 through page 6, line 18 and further in the Example on page 7, lines 13-20.

Applicants submit that the specification as originally filed, and the specification as amended to include the information previously identified as essential material (matter) by the

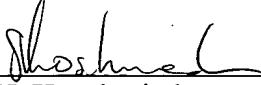
Office, teaches contacting the hydantoin of the present claims with a hydantoinase (e.g., as an enzyme expressed by, for example, *E. coli*), and further teaches the conditions under which the contacting may be carried out in the presence of the carbamoylase.

Applicants submitted a substitute Sequence Listing and a corresponding computer-readable Sequence Listing on April 24, 2004. The sequence information recorded in the corresponding computer-readable Sequence Listing is identical to the paper copy of the substitute Sequence Listing. Support for all of the sequences listed in the substitute Sequence Listing is found in the present application as originally filed on pages 12-17 and in U.S. 6,524,837 which was incorporated by reference in the specification as originally filed. No new matter is believed to have been introduced by the submission of the substitute Sequence Listing and the corresponding computer-readable Sequence Listing.

Applicants submit that the arguments presented above raise no new issues for consideration since the amendment to include matter described by the Office as "essential material" was identified as such in a previous Office Action. Applicants respectfully request the Examiner enter the amendment, reconsider the rejection and pass all now-pending claims to Issue.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Stefan U. Koschmieder
Registration No. 50,238

Customer Number
22850

Tel: (703) 413-3000
Fax: (703) 413 -2220
(OSMMN 08/03)